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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,932

11/09/2006

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20350 7590 02/26/2007
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EXAMINER

AEDER, SEAN E

ART UNIT

PAPER NUMBER

1642

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

02/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/572,932	Applicant(s) NAKAMURA ET AL:	
	Examiner Sean E. Aeder, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

It is noted that the claims of the instant application have been determined to include linking claims. Claim 1 link(s) inventions I-II, as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1 as drawn to MGC47816. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group I, claim(s) 2-7, as specifically drawn to methods of determining the expression level of MGC47816 polypeptide.

Group II, claim(s) 2-3 and 5-7, as specifically drawn to methods of determining the expression level of MGC47816 polynucleotide.

It is noted that the claims of the instant application have been determined to include linking claims. Claim 1 link(s) inventions III-IV, as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1 as drawn to HES6. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no

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longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group III, claim(s) 2-7, as specifically drawn to methods of determining the expression level of HES6 polypeptide.

Group IV, claim(s) 2-3 and 5-7, as specifically drawn to methods of determining the expression level of HES6 polynucleotide.

Group V, claim(s) 8, 11, 12, 20, and 24, as specifically drawn to a method of screening for a compound comprising the step of contacting a test compound with a polypeptide encoded by MGC47816 and a method of administering a compound identified by said method.

Group VI, claim(s) 8, 11, 12, 20, and 24, as specifically drawn to a method of screening for a compound comprising the step of contacting a test compound with a polypeptide encoded by HES6 and a method of administering a compound identified by said method.

Group VII, claim(s) 9-10, 13, 20, and 24, as specifically drawn to a method for screening for a compound comprising the step of contacting a candidate compound with a cell expressing MGC47816 and a method of administering a compound identified by said method.

Group VIII, claim(s) 9-10, 13, 20, and 24, as specifically drawn to a method for screening for a compound comprising the step of contacting a candidate compound with a cell expressing HES6 and a method of administering a compound identified by said method.

Group IX, claim(s) 14, as specifically drawn to a kit comprising a detection reagent which binds to the nucleic acid sequence of MGC47816.

Group X, claim(s) 14, as specifically drawn to a kit comprising a detection reagent which binds to the nucleic acid sequence of HES6.

Group XI, claim(s) 14 and 23, as specifically drawn to a detection reagent which binds to the polypeptide sequence of MGC47816 and a kit comprising said detection reagent.

Group XII, claim(s) 14 and 23, as specifically drawn to a detection reagent which binds to the polypeptide sequence of HES6 and a to a kit comprising said detection reagent.

Group XIII, claim(s) 15-17, 21-22, and 25, as specifically drawn to a method of administering antisense MGC47816 and a method of administering siRNA targeting MGC47816 and a product comprising siRNA against MGC47816.

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Group XIV. claim(s) 15-17, 21-22, and 25, as specifically drawn to a method of administering antisense HES6 and a method of administering siRNA targeting HES6 and a product comprising siRNA against MGC47816.

Group XV. claim(s) 18, as specifically drawn to a method of administering an antibody, or fragment thereof, that binds to a protein encoded by MGC47816.

Group XVI. claim(s) 18, as specifically drawn to a method of administering an antibody, or fragment thereof, that binds to a protein encoded by HES6.

Group XVII. claim(s) 19, as specifically drawn to a method comprising administering a polypeptide encoded by MGC47816.

Group XVIII. claim(s) 19, as specifically drawn to a method comprising administering a polypeptide encoded by HES6.

Group XIX. claim(s) 19, as specifically drawn to a method comprising administering a MGC47816 polynucleotide.

Group XX. claim(s) 19, as specifically drawn to as specifically drawn to a method comprising administering a HES6 polynucleotide

The inventions listed as groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-XX appears to be that they all relate to the special technical feature of methods of diagnosing hepatocellular cancer (HCC) comprising detecting MGC47816 or HES6.

However, PALM (US 2003/0092009 A1; 5/15/03) teaches methods of diagnosing hepatocellular cancer (HCC) comprising detecting HES6 (see paragraphs 76, 21, and 28, in particular)

Therefore, the technical feature linking the inventions of groups I-XX does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-XX are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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